EXHIBIT C

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

Master File No.
2:12-MD-02327

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

The deposition of LARRY T. SIRLS, II, M.D.,
Taken at 41000 Woodward Avenue, Suite 200 East,
Bloomfield Hills, Michigan,
Commencing at 9:33 a.m.,
Thursday, July 21, 2016,
Before Cheryl McDowell, CSR-2662, RPR.

Page 14

Doctor Sirls, who put together this binder for you?
A. That binder was put together by Butler Snow.
Q. Okay. And who chose the articles that went in this binder?
A. I did.
Q. Okay. And did you communicate to Butler Snow which articles you wanted included here?
A. Yeah. In my report we have these references, but then there are additional references that are not in my report that are in that folder.
Q. Okay. Is everything that's in here reflected in your reliance list?
A. Yes.
Q. Okay.
A. It should be to the best of my knowledge, it should be, yes.
Q. And in the process of putting together your report in this binder, did Butler Snow suggest or direct you to any articles that they published for you to look at or to include in this binder specifically?
A. No.
Q. Looking at Exhibits 4 and 5, those are internal Ethicon documents.

Page 15

Now, Doctor, you didn't have any access to these documents prior to being retained by an expert -- as an expert for Ethicon, correct?
A. Yes, correct.
Q. Okay. And these are documents that you reviewed in connection with your expert report, correct?
A. These are documents that I reviewed to make me understand the process and understand what was going on within the company.

It is not part of my expert report. My expert report is based on the literature.
Q. Okay. And the types of documents that you've given me in Exhibits 4 and 5, those are not the types of documents that you would customarily rely on to do your work in your peer-reviewed publications, correct?
A. These documents inform me, and I find them interesting.
Q. Okay.
A. It is not something that I use for my report, for my expert report.
Q. Okay. So I'm asking you something that's a little bit different.

You as a clinician and academic publish a

Page 16

number of peer-reviewed articles, correct?
A. Yes.
Q. And you've published a number of peer-reviewed articles on a wide variety of topics, correct?
A. Mostly pelvic reconstructive surgery.
Q. Okay. And lots of different subtopics, though, within pelvic reconstructive surgery, correct?
A. Yes.
Q. And in publishing those articles and prior to working as an expert for Ethicon, you've never consulted internal industry or company documents for any of the academic writings that you personally have done, correct?
A. Prior to receiving these documents, I had not reviewed documents like this in my academic work.
Q. Okay. And when were you provided with these documents?
A. I don't know exactly. Probably seven to nine months ago.
Q. Okay. And who selected these internal documents?
A. Butler Snow.
Q. Okay. And Butler Snow gave you a series it looks like of about a hundred and fifty or so internal Ethicon documents, give or take a few, is that

Page 17

correct?
A. So some of these are internal documents. Some of these are federal regulations. Some of these are publications or abstracts or discussions. Some of these are IFUs.

So there are a variety of different materials in those books.
Q. Okay. I just want to make sure that I'm conceptually getting that right.

Would it be fair to say that what's in Exhibit 8 which are the medical articles, those are the medical articles that you personally selected as reliance for your report, is that right?
A. That's part of it, correct.
Q. Okay. And then what is included in 4 and 5 are things that the lawyers for Ethicon gave you to review in connection with your expert report, is that right?
A. I want to clarify my earlier answer.
Q. Sure.
A. And that is that in this there are IFUs and things that I had and was aware of and had read before they were given to me.
Q. Okay.

Page 26

specific last summer, fall, and one for a TVT-O specific that we'll discuss today.

Is that the entire --

A. To the best of my knowledge, yes.

Q. Okay. And what did you do to prepare for your deposition today?

A. I reviewed my materials, my report, the binders you see in front of me, met with Mr. Koopmann.

Q. Okay. How many hours did you prepare for your deposition?

A. For the deposition?

Q. Yes.

A. Well, I'm probably -- so does that include reviewing all of this?

Q. Uh-huh.

A. Okay. Include writing up a report?

Q. No. Anything you've done specifically to prepare for sitting here today and answering questions.

A. Would that include reviewing the documents for the case, correct?

Q. Whatever you did.

A. So my report, I probably spent close to ninety hours on my report.

Q. Okay.

Page 27

A. Reviewing additional documents, and I haven't tallied up, so I'm giving you a generality.

Q. Sure.

A. I could be off a little bit. Reviewing the binders that we see in front of us, the literature, et cetera, another seventy hours or so. And then the case-specific medical records, probably in the thirties that I've done with that, and then I've met with Mr. Koopmann probably somewhere between fifteen and twenty hours.

Q. Okay. So if I'm doing my math right, it looks like you spent anywhere between two hundred and five to -- let's say two hundred to two hundred and ten hours total drafting your report, doing the case-specific report, reviewing your medical records, and reviewing the documents for the deposition, is that about right?

A. Somewhere in there.

Q. Okay. And we've had marked now the most current copy of your CV.

And is this a complete and accurate statement of your educational background and your training?

A. Yes.

Page 28

Q. Okay. Now, you did a fellowship with Doctor Zimmern in Los Angeles from 1992 to 1993, is that correct?

A. The lead, the lead physician in the fellowship was Gary Leach. Phillippe Zimmern was an associate.

Q. Okay. And how closely did you work with Doctor Zimmern at that time?

A. Very closely.

Q. Do you currently have a teaching appointment at any educational institution?

A. I am the fellowship director at Beaumont Health for female pelvic medicine and reconstructive surgery. I direct urology research for the residency program in the same institution. I'm a professor in urology at Oakland University William Beaumont School of Medicine.

Q. Okay. And do you currently act as a peer reviewer for any medical journal?

A. Yes.

Q. And what medical journal is that?

A. The Journal of Urology, the Urology, Neurourology, Urodynamics, Female Pelvic Medicine and Reconstructive Surgery.

Q. Okay. Now, you offer your opinions in this case as a clinician and a medical doctor, correct?

Page 29

A. Clinician, medical doctor, academician.

Q. Okay. And it's based largely on your clinical experience, correct?

A. Clinical experience, literature, discussions with friends, colleagues, meetings, et cetera.

Q. And you're not holding yourself out as an expert with regard to the material science of polypropylene, correct?

A. I have done a lot of literature review on the material science. It's very important in my practice because I use these materials, and I would say that I am a clinical expert in the use of these materials, their outcomes, their complications, et cetera.

Q. Okay. Now, you gave a deposition before, correct?

A. Yes.

Q. And have you reviewed that deposition in preparation for your deposition here today?

A. No.

MS. FITZPATRICK: Okay. So why don't we go ahead and mark this as Exhibit 9.

(Sirls TVT-9 marked and attached.)

BY MS. FITZPATRICK:

Q. Go ahead and take a look at that, Doctor. I'd like

Page 30

you to look at page forty-two, line seven through ten.

And you were asked at that time: You don't hold yourself out as an expert with regard to material science of polypropylene mesh, is that correct? And you answered correct.

Are you changing your testimony today?

A. Yes, I am.

Q. Okay. And tell me what you've done between December 12th, excuse me, December 14th, 2012, and today that changed you from not being an expert about material science with regard to polypropylene mesh and to now holding yourself out as an expert on that specific topic.

A. So during this deposition, this one that we're talking about, it's the first time I've been involved in the process like this, and I was naive and really did not understand the questions so well.

In that time it's been three and a half years. These products have come under much more scrutiny, and I have gone to the literature, talked to my friends, et cetera, gone to meetings, and have become much more educated with regard to these materials.

Page 31

So I state that I am a clinical expert in the use and clinical evaluation and outcomes of these products.

Q. Okay. Well, what I'm trying to get at is I understand that you're here as a clinician to talk about the use and the medical outcomes that come with using specifically the TVT and the TVT-O device, correct?

A. Yes.

Q. What I'm trying to get at is beyond that, those clinical opinions that you hold and that you've reported here, do you hold yourself out specifically as someone who is an expert in the material of polypropylene itself?

A. I have reviewed thousands of pages of documents in preparation, and I have reviewed quite a bit on degradation, FDA regulations, preparation, et cetera.

I think that I probably know more about the use of these products than many of the engineers who write these reports because I'm the one who's putting them in patients and evaluating their outcomes. So, yeah, I feel I'm extremely well versed and expert in using these products.

Page 32

Q. Okay. But I'm not asking you whether you're an expert in the use of the products and whether you're an expert in the clinical outcomes and implanting them in women.

Maybe let me ask you this. How many different kinds of polypropylene are there in the world?

A. So polypropylene is a polymer that I want to make sure I understand your question.

Do you mean how many makers are there?

Q. How many different types?

A. I don't understand your question.

Q. Do you know that there's different grades of polypropylene?

A. What do you mean by different grades?

Q. This is what I'm actually trying to get at. It seems to me from your expert report that you are an expert sitting here to tell me about the clinical implications and uses of polypropylene mesh products, particularly the TVT and the TVT-O, in women. That's what I got from your expert report, okay?

What I'm trying to get at is whether you are also an expert on the chemical and physical

Page 33

properties of polypropylene, polypropylene material generally, not in a clinical setting, but just there's people who specialize in polymers and plastics.

Are you one of those people?

A. I don't specialize in polymers and plastics.

Q. Okay.

A. But I'm informed and educated about many of these issues with polypropylene materials.

Q. Okay. Great. Tell me about the different grades of polypropylene.

A. What I can tell you is that prolene mesh is different than polypropylene because it's treated, right, with antioxidants.

Q. And what are those antioxidants?

A. Santanox and DTL-DP.

Q. And tell me how a manufacturer decides what concentration of antioxidants should be used in a particular polypropylene product.

A. I don't know that.

Q. Okay. Tell me the difference between the polypropylene that is used for an Ethicon product versus a polypropylene that is used for a Boston Scientific product.

Page 42

A. Our hospital has a policy on all material explants, and it goes to the pathology lab and we get a pathology report. They do not study the polypropylene for degradation.
Q. Okay. So in your clinical practice, you don't have any experience in reviewing pathology or looking at pathology microscopically for degradation, is that right?
A. I have not done it in my clinical practice on materials that I've explanted.
Q. Okay. Have you done it in another way in your clinical practice?
A. Clinical practice to me means reading the literature and understanding things. So it's just in the literature and discussions. That's where my information's coming from.
Q. Maybe this is where we're talking a little past each other. Just by way of shorthand, when I talk about your clinical practice, I'm talking about your actual treatment of women, okay? When we talk about your academic practice, I'm talking about your knowledge of the literature and the articles you write and all of that type of stuff. So I want to focus solely on your clinical practice.

Page 43

There's nothing in your clinical practice of treating women where you've done anything to specifically look for or study degradation of polypropylene mesh explants, correct?
A. Correct.
Q. And so your knowledge comes from reading somebody else's articles in the medical and scientific literature, is that right?
A. Yes.
Q. Okay. You started using the TVT device in 2005, correct?
A. Yeah. It may have been 2004. I'm sorry. It's in that time period.
Q. Okay. And prior to using a new medical device, you personally as a physician would want to be convinced that the device was safe and effective, correct?
A. Yes.
Q. Okay. And you wouldn't use personally a medical device that didn't have a proven track record of safety?
A. Well, so that's where surgery is a little bit different than, for example, medications that can be powered and randomized in large studies. In surgery we will often do procedures that do not have a large

Page 44

clinical experience because they're logical to us, they're intuitive, and we think that it may be an upgrade over what we're doing.
For example, I'm starting a study next month where I'll be implanting a device that's never been done before like this, and I'll be the first one doing it. There's no data on that.
Q. Okay. Is that part of a clinical trial?
A. In that case it will be.
Q. Okay. And that's a case where you tell the women or men who are getting this new device that they are part of a clinical trial, correct?
A. That is correct.
Q. And you'll tell them that they are getting a device that doesn't have an established record of safety, correct?
A. That's correct.
Q. And you'll tell them they are getting a device that doesn't have an established record of efficacy, correct?
A. So let me also back up to your prior question on safety. When we do these, we have typically very similar things that have been done that have been shown to be safe and effective. So we're not going

Page 45

in and doing something that we don't have a concept of safety and efficacy for.
Similarly, when we do surgical implants, from my first TVT or my first TOT, they were not in a clinical trial, and I had to tell my patient, look, this is my first one, but this is why I'm doing this, it's logical.
Q. And so with your first TVT and TVT-O that you did, prior to implanting those devices, did you do a review of the medical and scientific literature to satisfy yourself that the procedures and the devices were safe?
A. Yeah, that's a really good question because, as you know, the procedures were developed in '96, '97, '98, and I did not put my first one until 2004, 2005. So I was very cautious and I waited and watched the literature.
We're talking about TVT, right?
Q. Yes.
A. TOT was later, 2001, 2002, 2003. So, you know, I was very cautious and watched the literature. So I did do that exactly before, before I implanted it in my first clinical patient, and I was very comfortable.

Page 46

Q. Okay. So it was important to you that you had scientific data before implanting the TVT device into women, correct?
A. Again, there are different degrees of comfort and different amounts of data that are necessary before a surgeon feels comfortable doing something.
But, yeah, typically before I'm going to do it on my patient, I will have some literature, some discussions, some meetings, some information that makes me feel comfortable moving ahead.
Q. And you did that with the TVT device, right?
A. I did.
Q. And you did that with the TVT-O device, right?
A. I did.
Q. What literature did you rely on to satisfy yourself that the TVT was safe before you started using it?
A. The literature that would have been published at that time. I don't recall what was published at that time in that time period. I was watching very actively because I was skeptical, I was very skeptical.
But, let's see. It was Nilsson, Ulmsten, and then the people in the states. Who were the early TVT people? Maybe Dennis Miller, maybe Vince

Page 47

Lucente. I don't recall who were the major publishers in that time period.
Also at the meetings, the meetings are very important for us. People come up, they give their presentation, we're able to talk informally, and that helps me quite a bit.
Q. Okay. And did you receive information from Ethicon prior to using the TVT?
A. So what I would have done is I would have had to had some training by Ethicon and/or some mentoring by Ethicon before doing that. I would have gone to a cadaver lab or would have gone to a surgeon's home site and observed or done both.
I apologize. I don't recall because it's just been so long ago. But I recall doing all of these things, cadaver labs, visiting surgeons, watching them do them.
I had done a lot of surgeries, so I was pretty comfortable with these techniques. We use trocars all the time when we do slings and other things.
Q. I'm asking you specifically, though, about Ethicon.
A. Okay.
Q. Okay. What information did you receive from Ethicon

Page 48

prior to implanting your first TVT?
A. So what the information I probably would have received from Ethicon at that time would have been probably a booklet or a slide deck on the procedure. Of course, there's the IFU.
And primarily it's the literature, my friends. I don't rely as much on slide decks, IFUs, as I do on these other sources of information.
Q. Okay. But you do look at the information, I think you previously testified that you look at the information the medical device manufacturer would give you prior to implanting their product, correct?
A. Yeah. It may not be important to me, but, yeah, I look at it.
Q. And you would expect that Ethicon would fully disclose to you all of the risks that it knew of, it knew were associated with the TVT product, correct?
MR. KOOPMANN: Object to form.
THE WITNESS: As a surgeon who had done, I don't know, a thousand slings before I did my first TVT, I really don't need Ethicon telling me the risks and complications of sling procedures. They would have to tell me something that would not commonly be known to me.

Page 49

BY MS. FITZPATRICK:
Q. So a medical device -- so your testimony is a medical device manufacturer does not have a responsibility to tell physicians who are using its product of the risks it knows are associated with the product, is that what you're saying? There's no obligation to do that?
MR. KOOPMANN: Object to form.
BY MS. FITZPATRICK:
Q. I mean, they either have to tell you or they don't. I just want to know which one you think it is.
A. I think that they should tell us risks that would not commonly be known to surgeons and that would be unique to their device.
Q. And you realize, Doctor, that not everybody who's used a TVT has the same level of experience implanting a thousand slings before they started using a TVT device, correct?
A. Probably.
Q. And not every physician has the opportunity that you do to go to all of these meetings and to meet with all of your colleagues, correct?
A. I'm not sure. Probably.
Q. Okay. And you realize that where you practice and

Page 54

the mid-urethral sling which is why the whole world went to mid-urethral slings.
Q. Your hands are not everybody's hands, though, correct?
A. Yes.
Q. And you recognize there are reported complications that are unique to mesh slings that are not reported in association with fascial slings, correct?
A. Those complications in my mind would be entirely mesh related --
Q. Okay.
A. -- and nothing else.
Q. And nobody -- not everybody has the same results with polypropylene mid-urethral slings that you have, correct?
A. Interestingly, as I look at the meta-analyses, the data that I see is pretty consistent with my experience.
Q. Okay. So you're pretty middle of the road, you get the same results that other people do, is that right?
A. Yeah. I would say that my results are similar to what we see in the very large studies.
Q. Okay.

Page 55

A. Some, you know, some differences, but --
Q. Well, we will -- I want to look at some of those in a little bit.
A. Okay.
Q. But before we get there, so you do fascial slings.
What retropubic slings do you use?
A. I use the TVT Exact.
Q. And what obturator slings do you use?
A. I use the Abbrevo.
Q. And the Abbrevo is a different or a modified version of the TVT-O, is that right?
A. I look at the Abbrevo as an upgraded product. When you come out, when you have experience and you have time to reflect and think about the technologies, the next generation is often slightly improved over the first. So --
Q. Is the Abbrevo an updated improvement over the traditional TVT-O in your opinion?
A. I like the Abbrevo. It's my sling of choice now for many, many reasons. In fact, it's my primary sling of choice. I prefer that over retropubic slings.
But if the Abbrevo were off the market tomorrow and all we had was TVT-O, I would use that.
Q. Okay. Well, let's say how many sling surgeries do

Page 56

you do a year?
A. I'm not sure. A hundred. I don't know. Two hundred. I'm not sure.
Q. Okay. Let's try to just break it down. How many roughly percentage-wise if you can give me, how many of the slings that you implant are the Abbrevo?
A. So my obturator approach, it's about ninety percent of what I do.
Q. Okay. And about how many are the retropubic?
A. The remaining. Well, maybe nine percent to probably one percent, maybe two percent fascial slings at this time.
Q. Okay. And you agree with me the fascial sling is within the standard of care even though it's not your preferred surgical intervention, correct?
A. Yes.
Q. All right. So you offered a report on the TVT-O specifically.
What are the differences between the TVT-O and the Abbrevo product that you use?
A. So, first of all, let me just qualify that. In our field we tend to -- TVT-O has become kind of a very generic term. So sometimes I'll say TVT-O and what I mean is obturator sling.

Page 57

Q. Okay.
A. Okay. Just to qualify that.
Q. Okay. That's fair enough.
I want to talk very specifically about not TOT, not the transobturator slings generally but the Ethicon TVT-O device.
A. Okay.
Q. Okay. So the difference between the Ethicon TVT-O device and the Ethicon Abbrevo device.
A. Yes.
Q. What are the differences?
A. The differences are first that the Abbrevos or Abbrevos are all laser-cut mesh.
That's not as important to me clinically. The most important thing to me clinically is it's a shorter length.
Q. And having a shorter length, it doesn't go as far out into the groin and thigh, correct, as the traditional TVT-O?
A. Correct.
Q. Okay. And what in your opinion is the advantage of having the shorter length of the Abbrevo versus the TVT-O?
A. That's actually a really important issue, and the

Page 58

concern is groin pain, and clinically, I see this very infrequently but I still worry about it because this is a quality of life procedure, and I'm trying to make sure my patients are happy when we're done.

And although I see, again, I would say extremely infrequent groin pain that lasts more than a few weeks, if I can try and minimize that by having a mesh band that does not go through the adductor muscle group, then that's intuitive to me.

Q. Do you believe that the -- so your primary reason is you believe that there's a decrease in the chance of a long-term groin pain in a woman.

Is that sort of my layperson's interpretation of what you're saying?

A. So it was really an intellectual decision because clinically I was not seeing problems with groin pain. I mean, it was very, very infrequent. We talk about it in the literature, we see it in conferences, and it had my attention. The numbers are very low, but I worry about it. You worry. That's what I do.

So when the shorter mesh came out, I looked at it, I said this is logical. Maybe if I have one patient in a thousand who has that

Page 59

complication and I can prevent that one patient in a thousand from having it, I'd like to do that.

Q. Okay. And is there anything else that recommends the Abbrevo over the TVT-O device to you?

A. No.

Q. Okay. Do you even implant the TVT-O at all, or do you just use the Abbrevo at this point?

A. At this point I use the Abbrevo. If we don't have it, I'll use a TVT-O.

Q. Okay. And when did you change from the TVT-O to the Abbrevo?

A. I'm sorry. I'm not sure. A few years ago, a couple few years ago.

Q. Okay. Now, so a woman comes in to see you and she needs a surgical intervention for stress urinary incontinence. You offer her three potential procedures, the Abbrevo, the TVT Exact, and the fascial sling.

Those are your three options, is that right?

A. Well, there's another surgical option that's periurethral injection.

But we're -- I'm assuming that we're talking about a patient with simple, straightforward

Page 60

stress incontinence, and if that's the case, those are the three procedures we discuss.

Q. Okay. And why do you use the TVT Exact over just the TVT-O?

A. There's two scenarios where I might do that. Number one is if the patient has had a prior mid-urethral sling, there's some data, not great data, but there's some data that argues that a retropubic vector improves overcomes over the obturator vector in that specific subgroup.

The second reason would be if the patient has dyspareunia or pelvic pain, and what I would do in that patient is on exam, I would feel their pelvic floor muscles, and if they have any evidence of pelvic floor muscle pain or discomfort, I would not use an obturator sling in that patient.

Q. Okay. I think I misspoke. I was going to ask you that question too, so you already gave me that.

Why would you use a TVT Exact over the TVT-R?

A. I thought you said TVT-O.

Q. I apparently did. I just misspoke.

A. Okay.

Q. So --

Page 61

A. TVT-R. I like the curve of the trocar and the hand movement, but that's personal preference. I've used them both.

Some people really like the big trocar. They feel they can guide it easier and have more control over it. I happen to like the other trocar. It's just personal preference.

Q. Okay. And so let's go back to the question that I asked and you answered. The primary reason -- I just want to get this in my mind. A woman comes in to you for a surgical intervention, okay?

Is your -- generally your first recommendation that they have the Abbrevo sling, and you only go to the TVT Exact or the fascial sling if there's some kind of reason why you don't think that the Abbrevo is particularly suited for that woman, is that right?

A. Yeah. There are a few things that I look at, but if there are none of the risk factors that I am considering, my first choice is an inside-out obturator sling which is the Abbrevo.

Q. Okay. And the risk factors that you discussed were women who already have some type of pelvic floor or pelvic muscle discomfort or dyspareunia, is that

Page 62

right?
A. Yes.
Q. And is there any other risk factor that you can identify for me that would have you recommend the Exact over the Abbrevo?
A. Yes. That is in a patient who will have had prior mid-urethral sling, and those patients, again, there's some literature, mostly case series and things, not great, no Level I evidence, that argues that the retropubic vector in those patients may be better than the obturator vector, but studies like that, you know, that are not large they've been proven wrong before.

For example, you know, when we looked at the retropubic versus the obturator sling, one of the big issues was if a patient has ISD, if they have severe leakage, is the retropubic sling tighter or not than the obturator, and I have to say I thought that it was, and I was in a group that thought that it was. There's papers that said it was, some papers said that it wasn't.

So when we did our large six hundred patient prospective randomized trial and then we evaluated those patients according to leak point

Page 63

pressures which is a severity of urethral dysfunction, we found that both slings worked exactly the same.

So that was the first really big study to inform us as a field that the obturator sling works as well as the retropubic sling in patients with severe dysfunction, so that's not something that I use.

Interestingly, when I go to the meetings, everybody at the meetings will say retropubic slings are tighter, and that's because they're not reading the literature.
Q. Okay. So I want to go back to my question. Dyspareunia, pelvic floor muscle dysfunction, that's one risk factor that would have you recommend the TVT-R to a small subgroup of your -- subpopulation of your patients, right?
A. So the retropubic sling instead of an obturator?
Q. Right. Prior mid-urethral sling, you would go to a retropubic over the obturator in that case, correct?
A. For now until that's proven to be wrong.
Q. Okay. Anything else, any other risk factors that would have you recommend to a woman that she have a retropubic as opposed to an Abbrevo device?

Page 64

A. Nothing that I can think of right now.
Q. Okay. And then you also do a very small number of fascial slings, is that correct?
A. Yes.
Q. Are those ever -- do you ever recommend a fascial sling to a patient?
A. I do.
Q. Okay. And in what candidates would you recommend a fascial sling or a polypropylene mid-urethral sling?
A. So the brilliant thing about the mid-urethral sling is that it's tension free. That was just a critical advance, and it's changed. It's been the single most important thing that has improved the side effect profile of these procedures.

The fascial slings are placed at the bladder neck, not the mid-urethra, and historically they have been what we call compressive and which means obstructive which means that the patients have higher urgency rates and higher UTI rates, all of which are proven in the literature.

So when I have a patient whose urethra is mobile, it's moving, then I can put a mid-urethral sling in them. The urethra moves, hits the sling, and it works. Dynamic kinking is what we would call

Page 65

that in the literature.

But when a patient is scarred and the urethra is not moving, then I have to take my sling and I have to take my sling to the urethra and compress it, and that, I'm going to place fascia because we don't put mesh under tension. Mesh under tension could erode into the urethra.

So a fascial sling is typically under a little bit more compression, and what we know is commonly we're obstructing these patients which leads, again, to a whole another set of side effects which sometimes for a patient is more bothersome than their leakage in the first place. So it gets to be a very tricky, tricky population.
Q. Okay. Now, regardless of what procedure you're doing, the Abbrevo, the TVT Exact, or the fascial sling, you discuss the options with your patients, correct?
A. Yes.
Q. And you give them informed consent, correct?
A. Yes.
Q. And what -- let's start with the Abbrevo. What are the risks that you tell your patients about that can be associated with the use of the Abbrevo device?

Page 90

That is unique to this.

Prolene may potentiate existing infection. The next one's on obstruction. We know that. Acute or chronic pain, any surgery we do can do that. Voiding dysfunction, that goes up with the bullet above. I don't know why they split that into two different bullets. Pain with intercourse, we know about that. Neuromuscular problems, again, same idea. We know about that. Recurrence, bleeding, revisions, and then the last one, a permanent implant that integrates into the tissue. So that is unique to this when they talk about mesh.

However, if I have to go in and take the Burch sutures out that eroded into a bladder or fascial sling is out that is obstructing, that can be a very difficult dissection as well.

Q. Let me ask you based on these adverse reactions that you just reviewed, is there any reason that you know of from your medical and clinical point of view, any reason that those adverse reactions that are identified in the post 2015 IFU could not have been included in the pre-2015 IFU?

MR. KOOPMANN: Object to form, foundation.

Page 91

THE WITNESS: So my understanding when you look at both federal regulations and guidelines on IFUs, it has to be something that is unique, that is unique to the procedure and not commonly known.

And that's kind of where the whole argument is here is that these things are commonly known. The only thing that is unique here are the ones that specifically deal with mesh. We know removing it's hard, but mesh exposure is unique to these products, yes.

BY MS. FITZPATRICK:

Q. It's not my question.

A. I'm sorry.

Q. Is there any reason based on your medical knowledge and your clinical knowledge, is there any reason why any or all of these adverse reactions that are identified in the 2015 IFU could not have been listed in the pre-2015 IFU? Are these new things that people didn't know about until 2015?

MR. KOOPMANN: Object to form.

THE WITNESS: So I can't really comment on what the people at Ethicon were thinking when they --

Page 92

BY MS. FITZPATRICK:

Q. I'm not asking you that. I'm asking, you are a clinician and a medical doctor.

A. Yeah.

Q. I'm not asking you -- there's no way you can know what Ethicon was thinking.

A. Right.

Q. I'm asking from a purely medical point of view, what was known in the medical community about potential adverse reactions to the TVT device. Is there any reason based on that body of knowledge that you have that any of these adverse reactions could not have been identified in an IFU prior to 2015?

A. So, I apologize, but, you know, your question could not have -- I'm getting thrown off by that.

Q. Is there anything new here that physicians didn't know prior to 2015?

A. No. In fact, I would argue that we could probably still have the same four bullet points here, and I would still be comfortable with that.

Q. Or we could also argue that each of these adverse reactions could have made it into the earlier IFU because they were known as potential complications and adverse events with the TVT, right? It could

Page 93

have gone either way?

A. But this is just, I mean, I don't know who selected these things. We don't have blood clot on here. We could have gotten into blood clot.

Q. We could go down to the other adverse reactions as well.

A. Yeah.

Q. I'm just asking you, Doctor, I don't care which IFU you like better.

A. Okay.

Q. I'm just asking you, is there any reason that you know of based on your knowledge of the medical and scientific literature that what Ethicon chose to put into its IFU in 2015 could not have been incorporated into an earlier version of the IFU based on medical and scientific knowledge? That's all.

A. You know, it's the could not. It's like a double negative.

So, so are you saying that Ethicon could have put these in earlier IFUs, is that a simpler way of saying it?

Q. Could Ethicon have put these adverse events into early IFUs?

Page 126

weight? Do you recall that?
A. So there's the Amid study which is the original study on pore size, Type I, Type II, Type III, Type IV.
I also looked at Pam Moalli's paper from 2008 --
Q. And is it your --
A. -- and many other articles and documents looking at pore size.
Q. That Moalli paper that you just referenced, that contains a table in it that lists the density and pore size of various incontinence slings?
A. Yes.
Q. And that's something you've reviewed?
A. Yes.
Q. You testified earlier today that you've explanted some polypropylene mesh slings or portions of some polypropylene mesh slings, is that right?
A. That's correct.
Q. And when you had occasion to do that, did you look at the mesh that you explanted?
A. Yes.
Q. In that gross examination of the mesh, did you observe any degradation?

Page 127

A. It looked normal to me.
Q. And does your outcomes with your patients in whom you've implanted a mid-urethral polypropylene sling like the TVT or TVT-O inform your opinion about whether or not the mesh in those slings degrades?
A. Yeah. I find it just, I find it so interesting to read these internal documents on mesh degradation because it was a surprise to me and because clinically I just have not seen any evidence of this at all.
We have long-term studies looking at patients looking at their clinical outcome, clinical outcome meaning continued improvement in symptoms but also meaning lack of progression of scar tissue, pain, discomfort, et cetera. So I just don't see any clinical evidence that this is an issue.
Q. There was some discussion earlier about what literature you relied on at the time that you started to use the TVT and at the time that you started to use the TVT-O.
Do you recall that generally?
A. Yes, yes.
Q. Did you also rely on the TVT literature that existed as something that made you feel comfortable that the

Page 128

TVT-O devices was safe and effective when you started using the TVT-O?
A. Yeah. So when the TVT-O came out, the idea was that it's the exact same mesh, it's the exact same location, it's just a different way of getting it there, and we were very comfortable with that.
Q. Do you offer the Burch procedure as a stress urinary incontinence treatment to your patients today?
A. I do not.
Q. Why not?
A. So we did a large prospective randomized trial on Burch, and it just, it's not, it's not durable. It's not effective. So when I would do it before, it was only when we were in the abdomen, and it was there, it was easy, we were in the abdomen, we would do a Burch.
But now when they're in the abdomen, if they need an anti-incontinence procedure, I'd do a mid-urethral sling. So I'll let them finish in the belly, close, then I'll go vaginally and I will do mid-urethral sling because they're more effective, and I think that they have a better safety profile.
Q. Have you actually seen lower rates of groin pain or leg pain with your TVT Abbrevo patients than you did

Page 129

with your TVT-O patients?
A. No. I really haven't. I haven't formally studied it, but anecdotally in my, just evaluation of my patients, I have not seen that. We do look at these patients when we do our trials.
I don't have a prospective sling database but I have retrospective sling databases, and we have not seen a difference.
Q. Does the TVT Abbrevo use the exact same mesh as the TVT-O?
A. No. The Abbrevo is a laser-cut mesh.
Q. But apart from the cutting technique, is it the same mesh?
A. Yes, it's the same mesh.
Q. And there's laser-cut TVT-O mesh, correct?
A. There is, that's correct.
Q. In addition to mechanically cut TVT-O devices?
A. That's correct.
Q. But the mesh in the TVT Abbrevo and the TVT-O is the same polypropylene?
A. Yes, it's the same weave, monofilament.
Q. It's the same weight or density?
A. Same weight, same pore size. It's a hundred grams per liter squared.

Page 130

Q. Does the mesh used in the two devices lay under the urethra at the same spot?
A. It does. We do that on purpose.
Q. Does the TVT Exact use the exact same mesh as the TVT with the exception of the cutting technique?
A. Yes, yes, it is.
Q. But, again, with the TVT there's also laser-cut mesh available, is that your understanding?
A. That's correct.
Q. And is the TVT Exact mesh the same weight and pore size as the TVT mechanically cut mesh?
A. Yes, it is.
Q. And that mesh lays under the urethra at the same place?
A. Yes.
Q. I'm going to ask you a couple of follow-up questions about Exhibit 11 and 12. 11 is the TVT IFU before 2015, and 12 is the TVT IFU before 2015.
A. Okay. I have them both.
Q. Which one do you have in front of you right now that you're looking at?
A. I have the TVT-O one.
Q. Okay. So if you look at the TVT-O marked as Exhibit 12, there was some discussion earlier about

Page 131

the adverse reaction section.
Do you recall that?
A. Yes.
Q. Right above the adverse reaction section, there's a section that says warnings and precautions, is that right?
A. Yes.
Q. And if you look at the fifth bullet point from the bottom of that list of warnings and precautions, it says: Transient leg pain lasting twenty-four to forty-eight hours may occur and can usually be managed with mild analgesics, is that correct?
A. Correct, yes.
Q. And then if you look at the Exhibit 11 which is the TVT IFU, before 2015, you don't see that same notation of transient leg pain, do you?
A. That's correct.
Q. So in that respect, would you agree that these TVT and TVT-O IFUs before 2015 do set forth a different risk profile?
MS. FITZPATRICK: Objection.
THE WITNESS: Yeah. I apologize for that. I will tell you that the print is so small, I can hardly see it even with my glasses on.

Page 132

However, I did not review that carefully enough before talking about that this morning, and it does clearly say that.
BY MR. KOOPMANN:
Q. And the TVT-O IFU on the first page, one of the things it says in a paragraph at the top of the first substantive page I'll call it that says English at the top, it says: The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the Gynecare TVT obturator device, is that correct?
A. Yes, that's correct.
Q. And if you go to the TVT IFU marked as Exhibit 11, it also says: The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the Gynecare TVT device, is that correct?
A. Yes, that's correct. And really, all these decisions are not -- these decisions are all made by the local hospitals, universities, et cetera, who do privileging, chairman of the department. That's how we decide who can implant and who cannot implant. It's a local decision made by the administrations

Page 133

and departments at the local hospitals.
Q. Is the fact that data can change over time one of the reasons surgeons continue to do studies and systematic reviews and meta-analyses?
A. Yeah, and I alluded to that in talking about how the literature develops, and we learn more and more things as time goes on.
Q. And is a continuing review of the literature something that surgeons do as part of their practice?
A. It's what we constantly do. In fact, in programs like ours, we have a journal club every month specifically to look at the new literature to keep ourselves updated.
Q. Can a risk profile of a device change over time?
A. Absolutely, especially as we learn more about it and we're informed.
Q. The additional adverse reactions and other adverse reactions that counsel went over earlier with you in the 2015 IFUs for the TVT and TVT-O which have been marked as Exhibits 13 and 14 respectively, in your opinion was there any reason that those additional adverse reactions that were not seen in prior versions of the IFU needed to be included in the

products versus AMS products, and what you told me, I did not do one at my institution but I participated in the overall study.
A. Yeah. So, so we did not do it at Beaumont, you're right. I participated in the study that pulled the data and looked at it on the national level.
Q. Those weren't your patients, right?
A. Some of them were but not all of them, no.
Q. You didn't do it at Beaumont?
A. We did not do a study at Beaumont where we compared Ethicon versus AMS or somebody else.
Q. And those are your patients who you haven't done a study in your patients at Beaumont that compared Ethicon to another manufacturer, right?
A. But what we did is we participated in the study that compared AMS and Ethicon on a national level.
Q. Okay.
A. But not on a local level.
MS. FITZPATRICK: That's all that I have. Thank you.

(Deposition concluded at 12:50 p.m.)

STATE OF MICHIGAN)
)SS.
COUNTY OF LIVINGSTON)

CERTIFICATE OF NOTARY PUBLIC

I certify that this transcript is a complete, true, and correct record of the testimony of the deponent to the best of my ability taken on Thursday, July 21, 2016.

I also certify that prior to taking this deposition, the witness was duly sworn by me to tell the truth.

I also certify that I am not a relative or employee of a party, or a relative or employee of an attorney for a party, have a contract with a party, or am financially interested in the action.

Cheryl McDowell, CSR-2662, RPR
Notary Public, Livingston County
State of Michigan
Commission Expires September 13, 2019